JUL 15 2002

K013713

510(k) Summary
as required by section 807.92(c).

Name: Ludovico Glavotto
President

Address: Amuchina International, Inc.
8-8 Metropolitan Court
Gaithersburg, MD 20878

Telephone: 301-330-7597
FAX: 301-330-6432

Contact Person: Ludovico Glavotto

Date Summary Prepared: 01 November 2001

Trade Name: ARM Automatic Reprocess Machine
Common Name: dialyzer reprocessing system
Classification Name: dialyzer reprocessing system, panel 78, procode LIF, unclassified

Legally Marketed Device claiming Substantial Equivalence to, §807.92(a)(3):

Seratronic DRS-4 Dialyzer Reprocessing System, K860674

Description of Device, §807.92(a)(4):

The Amuchina ARM Automatic [Dialyzer] Reprocessing Machine is a stand alone device designed for the automated reprocessing of hemodialyzers for reuse and for the pre-processing of hemodialyzers prior to first use. The ARM Unit has 4 stations which can sequentially process up to 4 dialyzers at one time. The ARM Unit has no direct or indirect patient contact.

The ARM Unit uses a peracetic acid/hydrogen peroxide based disinfectant as both a cleaning solution and a disinfectant. The disinfectant concentrate is diluted to the in-use strength with AAMI quality water.

When reprocessing dialyzers, the ARM Unit uses the following cycles: Rinse, Cleaning, Flush, Volume & Leak Test, and Disinfection. When pre-processing dialyzers, the following cycles are used: Flush, Volume & Leak Test (only if instructed for by the user), and Disinfection.

For regularly scheduled maintenance, the ARM Unit has the following system cycles: System Rinse, System Disinfect, and System Self Test. Other cycles which are included in the ARM Unit include: Prime Pump for priming the chemical pump with the disinfecting agent, Line Volume Calibration for use in determining the total cell volume of the dialyzer, and System Void to purge fluids from the circuits prior to moving the machine.

K013713

The ARM Unit incorporates the feature of including a patient photograph on the dialyzer label, thus reducing the possibility of reused dialyzers being used on the wrong patient.

Intended Use of Device, §807.92(a)(5):

The ARM Automatic [Dialyzer] Reprocessing Machine is a device to reprocess hemodialyzers for reuse on the same patient. The patient population are those patients who have End-Stage Renal Disease and are on chronic hemodialysis. The ARM Unit is designed to be either a stand-alone device or act as either a server or a slave Unit in a network of several ARM Units.

The ARM Unit also can pre-processes hemodialyzers prior to first use, where pre-processing is the medical policy of the health care facility.

Summary of Technological Characteristics of ARM Automatic Reprocessing Machine and the DRS-4 Dialyzer Reprocessing Systems, §807.92(a)(6):

Freature	Amuchina ARM	Seratronics DRS-4
Indications for Use	Reprocessing hemodialyzers for reuse and Pre-processing hemodialyzers prior to first use	Reprocessing Hemodialyzers for multiple use and Prepacking hemodialyzers for specific patients
Number of Processing Stations	4	4
Cleaning Solutions	Peracetic Acid/Hydrogen Peroxide	Peracetic Acid/ Hydrogen Peroxide Bleach/Sodium Hypochlorite
Disinfectants	Peracetic Acid/Hydrogen Peroxide	Peracetic Acid/Hydrogen Peroxide Formaldehyde
Cycles	Rinse, Clean, Flush, Test, Disinfect	Clean, Disinfect, Test
Test Cycle Includes	Pressure Leak Test Total Blood Cell Volume	Pressure Leak Test Total Blood Cell Volume Ultrafiltration Rate
Dialyzer Labels Processing for Reuse	Includes: Bar Code Patient Name Patient Photograph (digital) Dialyzer Lot Number Dialyzer Serial Number Number times reprocessed Number times reused Test Results Dialyzer Status	Includes: Bar Code Patient ID Number & Name Social Security Number Dialyzer Type (code #) Dialyzer Code Number times reused Test Results Dialyzer Status

K013713

Dialyzer Label Pre-processing	When Added to List for Pre-processing: Bar Code Status: Do Not Use Dialyzer Model Dialyzer Lot Number Dialyzer Serial Number After Pre-processing: Bar Code Dialyzer Lot Number Dialyzer Serial Number Number times reprocessed Number times reused	(No label printed. If pre-processing a dialyzer prior to first use, the DRS-4 system records the TCV, and the KUF values foe each dialyzer, and enters the results in the database.)
Microprocessor controlled	Yes	Yes
Interactive Touch Screen	Yes	Yes
Operator can define some parameters	Yes	Yes
Camera for Patient Photograph	Yes	No
Water Requirements: Pressure Quality Temperature Flow Drain Height	 30-115 psig AAMI Quality 15 – 25 degrees C up to 1500 ml/min at 2 bar up to 16 inches	 25-80 psig AAMI Quality 24-35 degrees C 1800 ml/min @ 1.75 kg/cm up to 16 inches max

Non-Clinical Performance Data, §807.92(b)(1):

Each individual function of the ARM Unit was tested to see if they performed as intended/programmed. No errors or failures ~~either~~ were detected and the performance characteristics of the down-stream processing procedures were not affected by the preceding test(s).

In-vitro testing was performed to assure the ARM Unit properly diluted the cleaner/ disinfectant concentrate to the in-use concentrations of active ingredients. The results from these tests show that the ARM Unit performed as expected.

Conclusions Drawn from Non-Clinical Performance Data, §807.92(b)(3):

The functionality tests on the ARM Unit demonstrate that the ARM Automatic Reprocessing Machine will perform as labeled for the reprocessing of hemodialyzers. The results of these tests demonstrate that the ARM Automatic Reprocessing Machine is substantially equivalent to the DRS-4 Dialyzer Reprocessing System, which is commercially distributed for the same intended use that is the reprocessing of hemodialyzers for reuse.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2002

Mr. Gary Mishkin
Vice President of Research
and Development
Alcavis International, Inc.
8-8 Metropolitan Court
GAITHERSBURG MD 20878

Re: K013713
Trade/Device Name: ARM Automatic
Reprocessing Machine
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LIF
Dated: April 12, 2002
Received: April 16, 2002

Dear Mr. Mishkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013713

Device Name: ARM Dialyzer Reprocess Unit

Indications for Use:

The Amuchina Automatic Reprocessing Machine (ARM) is a device designed for both (a) reprocessing hemodialyzers for reuse, and (b) preprocessing hemodialyzers prior to first use. Reprocessed hemodialyzer will be reused on the same patient on who originally used the hemodialyzer. Both the reprocessing and preprocessing procedures use peracetic acid/hydrogen peroxide based disinfectant.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013713

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)